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09/836,347	04/18/2001	William A. Kochring	N1239-008	8757

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KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/836,347	KOEHRING ET AL.
	Examiner David H Kruse	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-33 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

() Notice of References Cited (PTO-892) (4) Interview Summary (PTO-413) Paper No(s). _____.
() Notice of Draftsperson's Patent Drawing Review (PTO-948) (5) Notice of Informal Patent Application (PTO-152)
() Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 3. (6) Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 10 August 2001 and 15 October 2001 have been considered, copies of which are attached hereto.

Specification

2. The disclosure is objected to because of the following informalities: The deposit information on page 34 of the specification lacks any reference to the ATCC Accession number of inbred corn line RBO1.

Appropriate correction is required.

Claim Objections

3. Claims 16, 18, 23 and 33 are objected to because of the following informalities:

At claim 16, line 1, the phrase "said hybrid corn seed" should read -- the hybrid corn seed -- in referring to claim 15.

At claim 18, the phrase "The process" should read -- The method -- in referring to claim 17, directed to "A method".

At claim 23, line 2, the term "express" should read -- expressing --.

At claim 33, lines 4-5, it is unclear if there is a typographical error in the phrase "corn endosperm or quality", and that the phrase should read -- corn endosperm quality --. Clarification is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-33 are indefinite because the designation "RBO1" does not denote an art recognized designation of a corn plant and hence does not state the metes and bounds of the claimed invention. The ATCC Accession Number must be filled in where appropriate to clearly provide the identifying characteristics of Applicant's corn inbred line designated RBO1. Compliance with this requirement may be held in abeyance since Applicant's specification provides evidence that the deposit has been or will be made. Applicant must provide the appropriate amendment to insert the deposit information at the time of allowance in both the specification and the claims.

Claim 6 is indefinite because the plant of claim 2 is not male sterile. Amending said claim to replace "is male sterile" with -- further comprises a genetic factor conferring male sterility -- would obviate this rejection.

At claim 8, lines 1-2, the phrase "the cells or protoplasts of the tissue culture being from a tissue" is indefinite because it is unclear what the metes and bounds of "being from" are. In addition, the term "protoplasts" lacks a proper antecedent basis in the claim. It is suggested that the phrase read -- the cells or protoplasts of said cells having been isolated from a tissue --.

At claim 9, line 2, the phrase "is capable of expressing" is indefinite because it does not denote a positive characteristic of the claimed corn plant and thus does not

state the metes and bounds of the claimed invention. The term -- expresses -- is suggested.

Claim 10 is indefinite because the claimed product-by-process does not set forth any process steps by which the claimed product is made, the apparent step "using" at line 3 does not denote a positive method step or a complete method. In addition, at line 4 the phrase "such a process" is indefinite and should read -- said process --.

Claim 17 is indefinite because the end product of the claimed method is a "seed" and the method is directed to producing "inbred RBO1", not seed of the inbred corn line designated RBO1. In addition, at step d), the phrase "preserves the homozygosity of said inbred parent plant" should read -- regenerates said inbred RBO1 parent plant -- because the claimed method is directed to a method for producing and not a method of preserving the homozygosity of.

Claim 18 is indefinite because it is unclear if the step is replacing step (c) at claim 17 or further limiting said step.

At claims 19-25, the term "RBO1-derived" is indefinite because it is unclear from the instant specification what the metes and bounds of "derived" are. The instant limitation appears to be directed to RBO1-prodgeny. Clarification is required.

At claims 20, 23, 25 and 29, the terms "excellent seedling vigor", "early pollen shed", "excellent brittle stalk resistance", "superior root resistance" and "superior stalk resistance", for example, are relative and do not state the metes and bounds of the claimed invention.

Claim 24 is indefinite because it is unclear where in the method of claim 19 plant tissue culture methods are utilized, what the metes and bounds of "utilizing" said methods are, and how "derived progeny" are produced "utilizing" plant tissue culture methods. The claim is, in general, narrative and does not denote a positive method step.

Claim 25 is indefinite because the method of claim 24 appears to produce a further "derived" RBO1-derived corn plant, hence claim 25 does not properly further limit claim 24, but appears to be directed to the product of the method of claim 19.

Claim 27 is indefinite because the claimed method only recites the method step of "crossing" at line 2, but does not recite any additional step(s) leading to the production of a corn plant that contains in its genetic material one or more transgenes.

Claim 28 is indefinite because the method of claim 27 is indefinite for the reasons given above, hence there is no clear indication that "corn plants" are produced by the method of claim 27. In addition, the limitation "Corn plants" lacks a proper antecedent basis in claim 27 because the method is directed to making "a corn plant". Appropriate correction is required.

Claim 30 is indefinite because the claimed method of developing a corn plant using plant-breeding techniques does not recite any positive method steps by which one could practice the claimed method.

Claim 31 is indefinite because it fails to properly limit the method of claim 30. Claim 30 is directed to a method for developing a corn plant and not to a corn-breeding program. Hence, it is unclear what the metes and bounds of claim 31 are.

Claim 32 is indefinite because the method of claim 30 does not recite a method step by which a corn plant is produced, as discussed above.

Claim 33 is rejected as indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h). Specifically the phrase "resistance to bacterial, fungal or viral disease" at line 4 renders the claim indefinite. It is suggested that the phrase be amended to read - - resistance to bacterial disease, resistance to fungal disease, resistance to viral disease --.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "single gene conversion" in claim 33 is used by the claim to mean "moving a desired morphological and physiological characteristic via the backcrossing technique or via genetic engineering," (see page 8, paragraph 35 of the specification) while the accepted meaning is "a nonreciprocal event that occurs at or near the crossover point during reciprocal recombination." (see Darnell *et al* 1990, In Molecular Cell Biology, Scientific American Books, Inc. New York, New York, specifically page 478). The use of the term -- transgene -- would obviate this rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12-16 and 20-33 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to corn progeny plants and transgenic corn plants having undisclosed identifying characteristics whereby only the characteristics of the deposited corn line RBO1 are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. In addition, at claims 26 and 28 the effect of transgenes on the physiological and morphological characteristic of a transgenic RBO1 corn plant or progeny thereof, is not sufficiently described where by one of skill in the art could recognize the claimed corn plant. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection and transformation and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different plant. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification. To the extent that claim 33 reads on a corn plant comprising a "single gene conversion" wherein said "single gene" is introduced by a

backcrossing technique, it is unclear that Applicant could adequately describe such a plant because it is unclear that one of skill in the art could reproduce a RBO1 inbred corn plant that would have a single gene introduced by backcrossing from another, unidentified plant as broadly claimed (see below). While claims 20, 23, 25 and 29 set forth at least two RBO1 traits, because the terms used to describe the traits are relative terms, lacking a comparative basis (see 112, second paragraph rejection above), these traits do not adequately define or distinguish RBO1 progeny plants. Furthermore, neither the individual traits themselves, nor their degree of expression, appear to be unique to the deposited corn line RBO1. Accordingly, there is a lack of adequate description of the claimed progeny plants, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

8. Claims 17, 18, 27 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because Applicant has failed to adequately describe a hybrid corn plant, one of whose parents is inbred RBO1, as required to practice the method of claims 17 and 18, one of skill in the art would not know how to practice the claimed method and hence the claimed method is not

enabled. Similarly, because Applicant has failed to adequately describe the corn plant having been transformed so that its genetic material contains one or more transgenes as claimed in claim 26 as discussed supra, the method for producing a corn plant of claim 27 and the corn plant produced by the method of claim 27 at claim 28 are not enabled. One skilled in the art would not know how to use a plant that has not been adequately described.

9. Claim 33 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a corn plant having all of the physiological and morphological characteristics of the corn plant designated RBO1, said corn plant further comprising a "single gene conversion". This claim is being read to the extent that the "single gene conversion" has been achieved using a backcrossing technique as taught on page 8 of the instant specification.

Applicant only teaches the inbred corn plant designated RBO1.

Applicant does not teach the inbred corn plant designated RBO1, further comprising a "single gene conversion".

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of

working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Hunsperger *et al* (1996. US Patent No. 5,523, 520), Kraft *et al* (2000. *Theor. Appl. Genet.* 101:323-326), and Eshed *et al* (1996. *Genetics* 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger *et al* teaches that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (See column 3, lines 26-46). Kraft *et al* teaches that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (See page 323, column 1, line 7 to line 15). Kraft *et al* teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (See page 323, column 1, line 7 to line 15). Eshed *et al* teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (See page 1815, column 1, line 1 to page 1816, column 1, line 1).

Hence, given the limited guidance by applicant, the nature of the invention, the state of the art at the time of Applicant's invention, the relative skill of those in the art at the time of Applicant's invention, the predictability or unpredictability of the art, and the breadth of the claims, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to introgress a "single gene" using a backcrossing method and arrive back at the taught RBO1 inbred corn line having a "single gene conversion" as broadly claimed. Even producing a "single gene conversion" where the gene confers a characteristic selected from the group consisting of male sterility, herbicide resistance, insect resistance, resistance to bacterial disease, resistance to fungal disease, resistance to viral disease and corn endosperm quality would have required undue trial and error experimentation, given the unpredictability of the art as discussed supra.

Claim Rejections - 35 USC § 102/103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 12-16, 20, 22, 23, 25, 29 and 32 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Schuetz *et al* (U.S. Patent 5,932,787).

Schuetz discloses an inbred corn line designated SBB1 (see claims 1 and 2), which Applicant admits is similar to the inbred corn line of the instant invention (see page 10, paragraph 48 of the instant application). Said SBB1 inbred corn line inherently discloses such relative traits as "above average stay green", "early pollen shed" and "excellent brittle stalk resistance" (see for example, columns 5 and 6). Applicant should also note that because the limitations set forth in the claims lack a comparative basis as set forth in the 112, second paragraph, rejection above, these limitations are interpreted by the Office to be identical to those taught by Schuetz in the instant reference. While the inbred corn line of Schuetz is designated SBB1 and the inbred corn variety of the instant claims is designated RBO1, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art.

Schuetz does not specifically disclose a method of producing corn plants using RBO1 as a parent in an unspecified number of crosses with unspecified second parents.

The hybrid corn seed and hybrid corn plant of claims 12 and 13 would have been *prima facie* obvious to one of skill in the art at the time of applicant's invention because, depending upon what second inbred corn plant one of skill in the art had selected, the resulting corn seed and progeny could be genetically, morphologically and physiologically indistinguishable from that of the instant claims. Similarly, the corn seed

of claim 14 and the F1 hybrid seed and plant of claims 15 and 16 would have been obvious in view of the teachings of the Schuetz reference. The RBO1-derived corn plant of claims 20, 22, 23, 25, 29 and 32 would also have been obvious in view of the Schuetz reference because again, depending upon what second corn plant one of skill selects in producing said "derived" corn plant, the resulting progeny could be genetically, physiologically and morphologically indistinguishable from that of the claimed RBO1-derived corn plant, given the loss of RBO1-derived genetic material with each outcross to a non-RBO1 parent. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

13. Claims 1-11, 17-19, 21,24, 26-28, 30, 31 and 33 appear to be free of the prior art because it neither suggests nor teaches the LH295 inbred corn line of the instant claims or methods of use.
14. No claims are allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.
9 August 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

